Dr. Maureen Kamene
Division of Leprosy, Tuberculosis and Lung Disease (DLTLD)
Hospital Road, Kenyatta Hospital
Kenya

3 August 2017

RE: Urgent need to roll out LAM testing for TB in some people with HIV in Kenya

Dear Dr. Maureen Kamene,

As the acting DLTLD manager, we are writing to call on you to ensure the immediate introduction of a useful new test to detect tuberculosis (TB) in extremely vulnerable populations in Kenya. TB is one of the leading causes of death in Kenya. TB is particularly difficult to diagnose in people with HIV with low immunity or advanced disease, who are at extremely high risk of developing TB and dying from it. This is especially the case in Kenya, where 7,200 HIV-positive people die from TB per year, often before receiving a TB diagnosis. Fortunately, a simple, inexpensive new test called the lipoarabinomannan or LAM test, has demonstrated impact in this population.

The test, marketed as the Determine TB LAM Ag test by Alere, is a rapid point-of-care test that detects in urine the presence of an antigen specific to TB. As such, it is simpler to use and more sensitive in people with HIV than many other sputum-based diagnostic methods for TB, as sputum is difficult to produce, and extrapulmonary or paucibacillary TB disease are more common in people with HIV. The World Health Organization (WHO) recommends its use as a preliminary test to rule in TB in people with HIV with CD4 counts below 100/mm^3 or who are seriously ill. The Global Laboratory Initiative has also created a diagnostic algorithm that includes LAM. The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) now also supports the purchase of LAM.

LAM testing is the only TB diagnostic test to show a mortality benefit in a clinical trial. It is also the first truly point-of-care TB test to be recommended by the WHO. It has no infrastructural or biosafety requirements. And, at a cost of just USD $3.5 per test, it is very affordable.

A robust body of evidence supports the use of LAM in people with advanced HIV. A randomized controlled clinical trial demonstrated the utility of LAM testing in guiding TB treatment initiation and reducing mortality in people with advanced HIV. Researchers randomized over two thousand hospitalized people with HIV to receive either LAM plus routine diagnostic tests for TB (smear-microscopy, GeneXpert MTB/RIF, and culture) or routine diagnostic tests alone. The simple addition of LAM testing significantly reduced all-cause 8-week mortality by ensuring more patients were started on TB treatment and that treatment initiation occurred earlier.

Another recent study showed that LAM improves TB detection in HIV-positive adults with acute hospital admissions, regardless of whether they have TB symptoms. Using the LAM test on top of GeneXpert MTB/RIF doubled the yield from GeneXpert MTB/RIF alone. The study showed that routine urine LAM testing in newly admitted HIV-positive adults is feasible, provides major improvement in diagnostic yield with high specificity, is useful in identifying TB in people without respiratory symptoms and/or unable to produce sputum, and can rapidly identify patients at highest risk of death. A study led by Médecins sans Frontières (MSF) in Kenya also showed improved diagnostic yield of using urine LAM testing in hospitalized, symptomatic and ambulatory HIV-positive adults.[i] Though LAM is not a perfect test, the benefits of using it are many.

In the recent past there has been an improved response to TB and TB/HIV in Kenya, with Kenya being among the few countries in Africa that recently conducted a national TB prevalence survey and being the first country to roll out new child-friendly TB formulations among other noteworthy achievements. We urge you to continue in this vein and provide immediate access to the life-saving, simple, affordable intervention of LAM testing.

We request that you please work with the Ministry of Health to ensure the immediate procurement of this product urgently, its incorporation into testing algorithms, and its availability for use in people with advanced HIV throughout Kenya. We look forward to your assistance.

Please direct your response to Allan Maleche at amaleche@kelinkenya.org
Respectfully submitted,

Global TB Advisory Board (TB CAB)
Treatment Action Group
Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN)
Stop TB Partnership Kenya
ITPC